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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,596	08/13/2001	Todd K. Whitehurst	AB-125U	9185
23845	7590	06/07/2005	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			JASTRZAB, JEFFREY R	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/929,596

Applicant(s)

WHITEHURST ET AL.

Examiner

Jeffrey R. Jastrzab

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,14-21 and 25-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20,21,25-30,32 and 40-43 is/are allowed.
- 6) ☒ Claim(s) 1,3-11,14-19,31, 33-39, 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 3/14/05, with respect to the rejection(s) of claim(s) 1, 3, 5-9, 11-14, 16-18, 24-29, 31 and 32 under 35 USC 102(e) in view of Sawan et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Lue et al. and Fang et al.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 44-46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These are single means claims. A single means claim, i.e., where a means recitation does not appear in combination with another recited element of means, is subject to an undue breadth rejection under 35 U.S.C. 112, first paragraph. In re Hyatt, 708 F.2d 712, 714-715, 218 USPQ 195, 197 (Fed. Cir. 1983) (A single means claim which covered every conceivable means for achieving the stated purpose was held

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nonenabling for the scope of the claim because the specification disclosed at most only those means known to the inventor.

***Claim Rejections - 35 USC § 102***

Claims 1, 3, 4, 6, 11, 14, 15, 17, 31, 33-35, 37, 38, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Fang et al.

Fang et al. teach that the application of pulses to the sacral nerve roots creates a blocking potential that blocks naturally occurring action potentials from traveling downstream on the nerves, e.g. column 5 lines 32-39, thus the stimulation inhibits parasympathetic input via the blocking of natural excitation potentials. Urination control and fecal incontinence are addressed per column 1 line 5-11. As to Claim 11, since the excitation potentials can either be blocked or allowed to propagate both upstream and downstream (depending upon whether allowing voiding or preventing), the application of both excitatory and inhibiting pulses would be provided by the teachings of Fang et al.

Claims 1, 3-6, 11, 14, 15, 17, 31, 33-35, 37, 38, 44 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Lue et al. Lue et al. teach that the application of pulses to the nerves can influence by inhibition or facilitation (col. 8 lines 50-53).

Bladder control and fecal incontinence are addressed per column 4 lines 43-46. As to Claim 11, since the excitation potentials can either be inhibited or facilitated (depending upon whether voiding or preventing), the application of both excitatory and inhibiting pulses would be provided by the teachings of Lue et al.

***Claim Rejections - 35 USC § 103***

Claims 5, 10, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fang et al. Although the specific nerves claimed are not specifically addressed by Fang et al. it would have been obvious to one having ordinary skill in the art at the time of the invention to have stimulated any nerves appropriate to effect bladder or bowel control. As to Claims 10 and 16, the mere duplication of parts, i.e. adding more than one stimulator, to enhance the treatment effect would have been an obvious design expedient.

Claims 7-9, 18, 36 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fang et al. or Lue et al. in view of Sawan et al. Fang et al. and Lue et al. disclose the invention substantially as claimed less external control and charging and less feedback for stimulation control. Sawan et al. teach external control of a bladder and shrincter control device for the implicit benefits of avoiding the need of explantation for parameter adjustment and/or battery replacement. The incorporation of such into the Fang et al. or Lue et al. device would have been obvious in order to effect non-invasive transcutaneous control and rechargeability. As to the use of sensors to control parameter adjustment, Sawan teaches monitoring contact impedance to assure proper patient to electrode contact. The parameters are compared to stored values and the status is sent to the external controller which in turn controls stimulation parameters. Adopting the use of such feedback into the Fang or Lue et al. device would have been obvious in order to ensure that the electrodes are properly contacting the nerve target so as to provide the desired stimulation levels.

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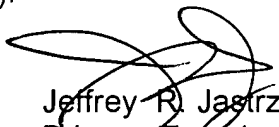
***Allowable Subject Matter***

Claims 20, 21, 25-30, 32, 40-43 are allowed for the absence of inhibitory stimulation pulses to a sympathetic target in the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Jastrzab whose telephone number is (571) 272-4947. The examiner can normally be reached on Monday - Wednesday 5:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Jeffrey R. Jastrzab  
Primary Examiner  
Art Unit 3762

6/3/05